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(71) Applicant (for all designated States except US): S.L.A.
PHARMA AG [CH/CH]; Gestadeckplatz 2, Postfach,
CH-4410 Liestal (CH).

(72) Inventor; and

(75) Inventor/Applicant (for US only): ARMSTRONG,
David, Nigel [GB/US]; 7410 Princeton Trace, Atlanta,
GA 30328 (US).(74) Agent: BURFORD, Anthony, F.; W.H. Beck, Greener &
Co., 7 Stone Buildings, Lincoln's Inn, London WC2A 3SZ
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ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,
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15 April 2004

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.(54) Title: TROPICAL FORMULATION COMPRISING AT LEAST 5% OF METRONIDAZOLE IN WHITE PETROLATUM
AND ITS USE IN THE ANAL AND RECTAL REGION(57) Abstract: A topical composition comprises at least 5-wt % metronidazole or a pharmacologically acceptable derivative thereof
in a non-aqueous vehicle. The composition may be used in the treatment of conditions of the colon, rectum, anorectum and perianal
region, in particular inflammatory bowel disease and perianal Crohn's disease. The composition also relieves pain and inflammation
and promotes healing of the colon, rectum, and anorectum and perianal region following surgical operations. One advantage of the
composition is that topical administration of metronidazole results in a primarily local effect and thus side effects observed from
systemic administration are avoided.

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INTERNATIONAL SEARCH REPORT

PCT/GB 03/03692

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K31/4164 A61K47/06 A61P17/02 A61P31/04 A61P1/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, MEDLINE, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	NYGAARD K ET AL: "Topical metronidazole treatment in pouchitis." SCANDINAVIAN JOURNAL OF GASTROENTEROLOGY. NORWAY MAY 1994, vol. 29, no. 5, May 1994 (1994-05), pages 462-467, XP009021238 ISSN: 0036-5521 page 462, column 1, paragraph 1 page 463, column 1, paragraph 6 - paragraph '0007! page 464, column 2, paragraph 2	1-28, 47-64
A	US 4 957 918 A (MARTIN NEIL F ET AL) 18 September 1990 (1990-09-18) examples 8-10 ----- -/--	1-28

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

Z document member of the same patent family

Date of the actual completion of the international search

27 November 2003

Date of mailing of the international search report

20.02.2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 386 960 A (AMERICAN CYANAMID CO) 12 September 1990 (1990-09-12) page 8, line 1 - line 6	1-28, 47-64
A	JAKOBOVITS J ET AL: "Metronidazole therapy for Crohn's disease and associated fistulae" AMERICAN JOURNAL OF GASTROENTEROLOGY 1984 UNITED STATES, vol. 79, no. 7, 1984, pages 533-540, XP009021239 abstract page 540, paragraph 2 - paragraph '0003!	1-28, 47-64

Form PCT/SA/210 (continuation of second sheet) (July 1992)

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INTERNATIONAL SEARCH REPORT

PCT/GB 03/03692

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
Although claims 48-64 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.
2. ☒ Claims Nos.: 1-7
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-28, 47-64

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

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FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210

Continuation of Box I.2

Claims Nos.: 1-7

Present claims 1-7 relate to an extremely large number of possible products. Support within the meaning of Article 6 PCT and disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the products claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the product comprising at least 5% of metronidazole and one of the vehicles listed on page 2, lines 19-23 of the present description.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-28, 47-64

Topical composition comprising at least 5% of metronidazole or a derivative thereof in a pharmaceutically acceptable non-aqueous vehicle and the use of this medicament in the topical treatment of diseases of the colon, rectum, anorectum or perianal region of the human or animal body

2. claims: 31-37

Use of metronidazole or a derivative thereof in the manufacture of a medicament for the topical treatment of diseases following a surgical operation to the colon, rectum, anorectum or perianal region

3. claims: 39, 45-46

Use of metronidazole or a derivative thereof in the manufacture of a medicament for the topical treatment of infective or inflammatory processes of the colon, rectum, anorectum or perianal region

4. claims: 40-44

Use of metronidazole or a derivative thereof in the manufacture of a medicament for the topical treatment of anorectal or perianal ulcers or skin defects

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INTERNATIONAL SEARCH REPORT

PCT/GB 03/03692

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4957918	A 09-09-1990	US 5614545 A	03-1997
EP 0386960	A 12-09-1990	GB 2229443 A	26-09-1990
		AU 632539 B2	07-01-1993
		AU 5076990 A	20-09-1990
		CA 2011423 A1	07-09-1990
		EP 0386960 A2	12-09-1990
		JP 2300114 A	12-12-1990
		NO 901048 A	10-09-1990

Form PCT/ISA/210 (patent family annex) (July 1982)

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